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Original article

Who are the normotensive acute pulmonary embolism patients with right ventricle dysfunction and normal cardiac troponin blood level?

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Abstract

Background. Current guidelines for acute pulmonary embolism (PE) management classify patients with heart right ventricle dysfunction (RVD) who do not have elevated cardiac troponin (cTn) blood levels as intermediate low risk patients. The aim of this investigation is to study the characteristics of these patients and the role of pre-existing cardiovascular diseases for the RVD.

Methodology. Out of 1675 patients with acute PE from the regional PE registry, we included 353 normotensive patients who had echocardiography imaging at presentation to hospital and normal blood levels of cTn. Patients were divided into low risk PE if they hadn't RVD and intermediate-low risk if they had RVD and their characteristics were compared.

Results. A 216 patients with low risk PE were significantly younger than 137 patients with intermediate-low risk. Arterial hypertension, chronic heart failure with reduced ejection fraction, coronary disease and diabetes mellitus type 2 were all significantly more prevalent in patients with intermediate-low risk ($p \leq 0.001$ for all comparisons) compare to low risk patients (77.4% vs 47.6%, $p<0.001$ for the presence of at least one of the four mentioned cardiovascular diseases). The age and sex adjusted odds ratio to have at least one of the mentioned cardiovascular diseases and intermediate-low PE was 2.954 (95%CI 1.658-5.266).

Conclusions. The majority of normotensive acute PE patients with RVD and normal cTn are actually chronic cardiovascular patients.

Key words pulmonary embolism, right ventricle dysfunction, intermediate-low risk patients

Introduction

Treatment of acute pulmonary embolism (PE) depends on the estimation of mortality risk as soon as diagnosis is established[1]. Patients with large thrombus burden and hypotension are at highest risk for dying from acute PE with hospital mortality above 20%[1,2]. In these patients' severe obstruction of a pulmonary circulation and impaired gases exchange lead to low left heart ventricle filling with hypo-oxygenated blood, and resulted with systemic arterial hypotension and hypoxemia. Patients may have acute right ventricle (RV) dysfunction because of the pulmonary artery circulation obstruction without hypotension, usually associated with elevated cardiac troponin (cTn) blood levels, and represent intermediate-high risk patients who could deteriorate, and become the high risk patients. Hospital PE-related mortality in intermediate-high risk patients is between 5-10%[2,3] which is higher than the hospital mortality of acute ST elevation myocardial infarction. Some patients have RV dysfunction but without the cTn blood elevation. According to European Society PE guidelines, these patients should be classified as intermediate-low risk patients, with low risk of dying from acute PE. However, is it possible that acute RV dysfunction, measured with cardiac ultrasound, or computed tomography pulmonary angiography (CTPA) could be presented without the elevation of the sensitive cTn assays? Or the RV dysfunction in these pa-

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tients is actually pre-existing state which is only aggravated in some degree because of the acute PE without severe pulmonary circulatory obstruction. If it is the case, the treatment of these patients should be more oriented to the pre-existing disease, or at least it could be modified because of that.
The aim of this study is to investigated the characteristics of patients with low risk and intermediate-low risk PE, and factors that could contribute to the RV dysfunction except the acute PE.

Methods

The patients were enrolled from the regional PE registry (REPER) which was founded in 2015, and till June 2022 year 1675 patients with computed tomography pulmonary angiography (CTPA) objectively confirmed PE, were recorded from the 5 university (Military Medical Academy Belgrade, Institute for Pulmonary Diseases Vojvodina, Clinical Centers Zemun, Nis and Kragujevac) and one general hospital (Pancevo) in Serbia, and 3 university cardiology clinics, from Banja Luka (Bosnia and Herzegovina), Podgorica (Montenegro) and Skopje (North Macedonia). Patients who were included into the study were classified as intermediate-low (only according to echocardiography estimated right ventricle dysfunction with normal blood level of cardiac troponin) or low risk PE using the ESC criteria published in 2019 guidelines[1]. We did not use pulmonary embolism severity score (PESI) or simplified version of this score (sPESI)[4] for the stratification of our patients as recommended, because we wanted to avoid the classification of patients according to mixed pre-existing comorbidities, age and the consequences of acute PE which are included in the scores. All patients must have normal cTn blood level at admission, and patients who were classified as intermediate-low risk PE must have echocardiography proven RV dysfunction.
We used modified criteria (slightly enhanced) for RV dysfunction as in pulmonary embolism thrombolysis trial (PEITHO) (5). Patient defined as having RV dysfunction if he had at least one of the criteria: systolic RV pressure > 40 mmHg (using Bernoulli equation $4xV^2$-regurgitation velocity + 10 mmHg), RV end-diastolic diameter > 3.5 cm measured from the apex 4-chamber view just below the tricuspid annulus, or tricuspid annulus plane systolic excursion (TAPSE) < 16 mm. Cardiac ultrasound imaging was performed as an initial diagnostic procedure in all patients.
During the admission process, detailed status of comorbidities was recorded. Patients who positive history of arterial hypertension and diabetes mellitus, treated or not, were considered as patients with arterial hypertension and diabetes mellitus. Patients who had myocardial infarction, any kind of myocardial revascularization or angiography objectivized at least one coronary disease, were considered as patients with coronary artery disease. Patients with left ventricle ejection fraction (EF) less than 50% were considered as patients with chronic heart failure with reduced EF. Patients who had history of decompensated heart failure with EF $\geq$ 50% were diagnosed as patients with heart failure with preserved EF. Malignant disease was considered if the patient was treated because of the malignant disease in the last six months before the acute PE or if the malignant disease diagnosed at the time of acute PE. Recent surgery was defined as any kind of surgery inside 21 days from the onset of acute PE symptoms. Glomerular filtration rate was calculated using Cockroft-Gault formula with the creatinine level at admission. Overweight and obese was defined as body mass index higher than 25 kg/m^2-29.9 kg/m^2, and 30 kg/m^2 and above, respectively.
Ethical committees or local review boards gave a permission to use the patient's data and to publish the results from the investigations derived from the REPER.

Statistical analysis

Basic characteristics of the patients as continuous variables are presented as means with standard deviation or medians with interquartile range depends on the normality of the data distribution which was tested with Kolmogorov-Smirnov test. Categorical variables are presented as frequencies and the significance of difference between the distribution of the data in low risk compare to intermediate-low risk patients were tested with Chi-square test. The significance of difference between continuous variables were tested with student t-test or Man-Whitney test, again depending on the normality of data distribution. Finally, a presence of at least one of the four cardiovascular co-morbidities (arterial hypertension, coronary artery disease, diabetes mellitus type 2 and chronic heart failure with reduced EF) was tested as a predictor of intermediate-low risk status with univariate and multivariate (odds ration adjusted to age and sex) binary logistic regression. P values less than 0.05 were considered as significant.

Results

From 1675 patients who were included into the REPER, 215 patients were hypotensive and classified as high risk PE, and 516 patients had RV dysfunction and elevated cardiac troponin levels and classified as intermediate-high risk PE, and they are excluded from the study. Among 400 normotensive patients who had RV dysfunction, 125 had only the CTPA established RV enlargement, and 138 patients did not have determined cardiac troponin at admission. Among the rest 544 normotensive patients at admission, 328 had no either complete echocardiography imaging or cardiac troponin measurement at admission. Therefore, 216 low risk and 137 intermediate-low risk PE patients who had both echocardiography imaging and cTn blood level at admission were included in the study.
The basic characteristics of patients are presented in table 1. Patients in intermediate-low risk PE were significantly older than patients with low risk PE. There are no differences between the distribution of sex, chronic obstructive pulmonary disease, stroke, recent surgery, malignant disease and chronic renal failure. However, patients in intermediate-low risk group significantly more often had chronic heart failure, arterial hypertension, coronary artery disease, diabetes mellitus and

Table 1. The basic characteristics of the study group

Characteristics	Low-risk N=216	Intermediate-low risk N=137	P
Age – y ± SD	55 ± 19	63 ± 15	< 0.001
Female sex – n, %	116, 53.7	67, 48.9	0.385
Comorbidities – n, %			
COPD	14, 6.5	9, 6.6	1.000
CHF	14, 6.5	26, 18.9	0.001
CHF with EF < 50%	5, 2.3	17, 12.4	< 0.001
Arterial hypertension	93, 43.1	99, 72.3	< 0.001
Diabetes mellitus type 2	22, 10.2	32, 23.4	0.001
Coronary disease	12, 5.6	22, 16.1	0.002
Previous stroke	12, 5.6	7, 5.1	1.000
Atrial fibrillation			
Paroxysmal during aPE	7, 3.3	11, 8.0	0.055
Permanent/Persistent	9, 4.2	10, 7.3	
Obesity or overweight[1]	96, 50.5	70, 64.8	0.021
Recent surgery	42, 19.4	18, 13.1	0.146
Malignant disease	22, 10.2	18, 13.1	0.395
GFR < 60 ml/min	55, 25.6	38, 27.7	0.710
Basic parameters at admission			
Systolic arterial pressure – mean ± SD mmHg	130.2 ±17.4	136.3 ± 21.8	0.004
Heart rate – mean ± SD bpm	88.4 ± 17.4	91.4 ± 22.0	0.160
Arterial pO_2 – mean ± SD mmHg	73.1 ± 21.0	73.6 ± 23.1	0.863
Arterial pCO_2 – mean ± SD mmHg	32.2 ± 7.6	30.9 ± 6.4	0.243
SPRV – mean ± SD mmHg	29.6 ± 7.6	52.7 ± 14.3	< 0.001
RV diameter – mean ± SD cm	2.9 ± 0.4	3.5 ± 0.6	< 0.001
EBSI – median (IQR)[1]	7.0 (5.0-11.0)	10.0 (7.0-12.0)	0.001
D-dimer – median (IQR)	3.1 (1.6-6.0)	3.4 (1.5-6.7)	0.786
CRP – median (IQR) mg/dl	49.6 (12.6-99.1)	34.5 (13.1-71.6)	0.221
Glycaemia – median (IQR) mmol/l	5.9 (5.25-6.9)	6.1 (5.3-7.65)	0.102
Elevated BNP or NT-proBNP[1] – n, %	24, 17.8	32, 40.5	< 0.001
Leukocytes – mean ± SD	9.6 ± 4.7	9.7 ± 3.4	0.892
Hemoglobin – mean ± SD	129.7 ± 19.9	129.6 ± 23.4	0.968
Total cholesterol – mean ± SD mmol/l	4.68 ± 1.16	4.61 ± 1.25	0.619

Abbreviations: COPD – chronic obstructive pulmonary disease, CHF – chronic heart failure, EF – ejection fraction, GFR – glomerular filtration rate, SD – standard deviation, SPRV – systolic, RV – right ventricle diameter, EBSI – embolic burden score index, IQR – interquartile range, CRP – C reactive protein, BNP – brain natriuretic peptide. [1]Missing values greater than 5%: obesity and overweight 26 (12.0%) and 29 (21.2%), EBSI 75 (34.7%) and 78 (56.9%), elevated BNP or NT-proBNP 81 (37.5%) and 58 (42.3%) for low-risk and intermediate-low risk, respectively

overweight or obesity compare to patients in low risk group. Both paroxysmal or long-standing atrial fibrillation were borderline significantly more frequently presented in intermediate-low than in low risk PE patients. A 77.4% of patients in intermediate-low risk PE compare to 47.6% of low-risk PE had at least one of the four cardiovascular comorbidities (figure 1), chronic heart failure with reduced EF (<50%), arterial hypertension, coronary artery disease, or diabetes mellitus type 2 (p<0.001). In the univariate logistic regression analysis, the presence of at least one of the four cardiovascular comorbidities compare to none of them, resulted to increase risk of having RV dysfunction which classify patients into the intermediate-low risk PE group (OR 3.784, 95%CI 2.318-6.176, p<0.001). This increased risk is also significant when adjustment to age and sex was done (OR 2.954, 95%CI 1.658-5.266, p<0.001).
All-cause hospital mortality rate was 5.1% in intermediate low risk, and 1.4% in low risk PE. Only 1 patient (0.8%) from intermediate low risk has died from PE according to our data.

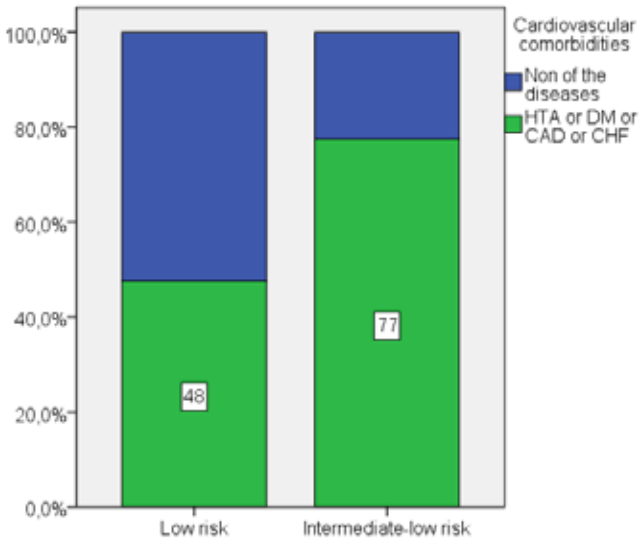

Figure 1. Frequencies of at least one cardiovascular comorbidities in low risk and intermediate-low risk aPE patients (p<0.001)

Discussion

The purpose of risk stratification in acute PE is to tailore the risk of therapy to risk of dying from PE. Therefore, patients in high risk group, who are hypotensive and have the highest risk for early dying from PE are treated with reperfusion therapy, mostly with systemic thrombolysis, if they have not absolute contraindication for that kind of therapy, which can very fast relieve the obstruction of pulmonary arteries and stabilized the patient's hemodynamics, but at the cost of almost five-time greater risk for major and fatal bleeding than anticoagulant therapy alone. Normotensive patients with RV dysfunction and elevated cardiac troponin represent the second step in the hierarchy of risk, who need close monitoring of vital parameters and in whom systemic thrombolysis can improve condition but the net advantage is doubtful taking into account that harm of major bleeding exceeds the benefit of thrombolysis. Intermediate low risk patients represent a heterogeneous group of patients. They may be defined only as sPESI score 1 and higher, and they may have either elevated cTn blood levels or RVD. Many of these patients have significantly impaired RV dysfunction which is actually not acute, and that is the reason why they have not increase of cardiac troponin which is very sensitive to acute stretching of the RV wall. Normotensive patients with acute PE and RVD without cTn blood elevation compare to patients without RVD have higher hospital mortality rate but rarely die from acute PE if they are properly anticoagulated[6].

The results from our study revealed that the majority of patients with intermediate-low risk PE, are actually chronic cardiovascular patients, and 77.4% of them had at least one cardiovascular disease, arterial hypertension, or coronary atherosclerotic disease, chronic heart failure with reduced EF or diabetes mellitus type 2. Those patients are in an increased risk of death during hospitalization because of acute PE compare to low risk patients[7]. They have diminished cardiopulmonary reserve which made them vulnerable to the less severe PE which can cause more damage in this subgroup of patients. We have already demonstrated that patients with chronic heart failure with reduced EF had higher hospital mortality than patients with normal heart independent of mortality risk estimated at admission and age[8].

The significance of define patients as intermediate low was not enough elucidated. There are only few data about the all-cause and PE-related death in this subgroup of patients. Becattini et al[2], tested the value of 2014 ESC mortality risk assessment, and the 30-day all-cause mortality was 20/333 (6.0%) of patients stratified as intermediate-low risk PE, and only 7 (2.1%) died from PE. In the smaller study of Cugno et al, mortality rate at 30 days in patients with acute PE diagnosis was 7/74 (9.5%) in the intermediate-low risk subgroup. The all-cause hospital mortality in the intermediate low risk subgroup of patients from our study was 5.1%. The presence of RV dysfunction without cTn elevation definitely mean higher early mortality in normotensive acute PE patients with OR 4.19 (95%CI 1.30-12.58) in the meta-analysis[7] of trials which studied the prognostic role of isolated cardiac troponin or RV dysfunction in low risk acute patients.

The majority of patients with RV dysfunction in our study had at least one of the four cardiovascular comorbidities. Arterial hypertension was the most common with 72.3%, following diabetes mellitus type 2 with 23.4%, coronary artery disease with 16.1% and chronic heart failure with reduced EF with 12.4%. All of this comorbidities are associated from the beginning with some degree of RV dysfunction which promote with the advanced stage of the disease.

In systemic arterial hypertension RV dysfunction began as a consequence of vascular pulmonary tree hyper-reactivity and myocardial fibrosis caused by over-reactivity of sympathetic and renin-angiotensin-aldosterone systems[9]. Left ventricle (LV) fibrosis and hypertrophy in arterial hypertension lead to progressive LV diastolic dysfunction and with time to mitral regurgitation and increase of pulmonary arterial pressure. Right and LV share interventricular septum which is very important for the normal function of RV[10]. Hypertrophic septum in arterial hypertension contribute to the dysfunction of RV. With long standing arterial hypertension, heart goes through the different stages of dysfunction, from asymptomatic phase which can be detected by the sensitive echocardiography techniques like global longitudinal strain, to heart failure with preserved EF and diastolic dysfunction of both chambers with atrial enlargement, and finely the heart failure with reduced EF and severely impairment of systolic function of both ventricles[11].

Even prediabetes is related to mild, but significant changes in RV function[12]. Overt diabetes with time is associated to heart failure which is a common evolution pathway in long-term diabetes[13]. Patients with diabetes mellitus type 2 and symptoms of heart failure with preserved EF have more frequently systolic and diastolic RV dysfunction than patients without diabetes. Finally, long-term diabetes, often associated with coronary artery disease lead to heart failure with reduced EF where RV dysfunction is even more prominent[14]. Diabetes is often associated to arterial hypertension, obesity and coronary artery disease which act synergistically and lead to myocardial fibrosis, oxidative stress, microvascular dysfunction, and resulted with impaired cardiac performance[14].

Coronary artery disease can cause necrosis and fibrosis of right heart with long-term RV dysfunction[15]. Atherosclerotic narrowing of right coronary artery may cause RV ischemia[16] which can be important for the RV failure in case of acute RV overload in acute pulmonary embolism. Heart failure with reduced EF is associated with significant RV dysfunction which is one of the main determents of the prognosis in these patients.

All these cardiovascular comorbidities, we mentioned, are in the interplay with chronic and cumulative dismal influence on RV function which can contribute to the acute RV failure in patients with acute RV afterload caused by pulmonary embolism.

Conclusion

Patients with acute PE who are normotensive and have some degree of RV dysfunction without cTn blood level elevation represent patients with high risk to suffer from

other common chronic cardiovascular diseases which could contribute to enhanced mortality risk in these patients compare to low risk PE patients.

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Sažetak

Ko su normotenzivni pacijenti sa akutnom plućnom embolijom, disfunkcijom desne komore i normalnim vrednostima troponina?

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Uvod. *Aktuelne preporuke za akutnu plućnu emboliju (PE) klasifikuju normotenzivne pacijente sa disfunkcijom desne komore (DDK) koji nemaju povišen srčani troponin (cTn) u intermedijarno-nisko rizičnu grupu Cilj ovog istraživanja je da ispita karakteristike ovih pacijenata i ulogu prethodno postojeće kardiovaskulatne bolesti na DDK.*

Metodi. *Od 1675 pacijenata sa akutnom PE iz regionalnog PE regsitra, u studiju smo uključili 353 normotenzivna pacijenta koji su imali ehokardiografski imidžing na prezentaciji u bolnicu i normalne vrednosti cTn. Pacijenti su podeljeni u nisko-rizičnu PE grupu ako nisu imali DDK I intermedijarno-nisku PE grupu ako su imali DDK.*

Rezultati. *216 pacijenata sa nsikim PE rizikom su bili značajno mlađi u odnosu na 137 intermedijarno-nisko rizičnih pacijenata. Arterijska hipertenzija, hronična srčana slabost sa smanjenom ejekcionom frakcijom, koronarna bolest I dijabetes melitus tip 2 su bili značajno češći kod pacijenata sa intermedijarno-niskim rizikom ($p \leq 0.001$ za sva poređenja) u odnosu na nisko rizičnu grupu (77.4% vs 47.6%, $p<0.001$ za prisustvo najmanje jende bolesti). Prilagođeno za godine i pol, rizik da pacijenti imaju najmanje jednu dodatnu kardiovaskularnu bolest je bio 2.954 (95%CI 1.658-5.266).*

Zaključak. *Većina pnormotenzivnih pacijenata sa akutnom PE, DDK i normalnim cTn zapravo imaju akutizaciju hronične kardiovaskularne bolesti.*

Ključne reči: *plućna embolija, disfunckija desne komore, intermedijarno-nizak rizik*