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ORIGINAL ARTICLE

Efficacy and safety of high dose versus low dose streptokinase for treatment of submassive pulmonary embolism

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Abstract Pulmonary embolism (PE) remains a major cause of morbidity and mortality in the general population, the established treatment for PE is anticoagulation. It has previously been demonstrated that thrombolytic therapy can be lifesaving in patients with massive PE (haemodynamic instability and right heart failure). However, the use of thrombolytic therapy in patients with submassive PE (haemodynamically stable) remains a controversial topic. Recent clinical studies, however, support evidence that thrombolysis may favorably affect the outcomes in a wider spectrum of high risk PE patients presenting with right ventricular dysfunction (RVD) as evidenced by decreased right ventricular end diastolic diameter (RVEDD), disappearance of paradoxical septal motion (PSM), and tricuspid regurge (TR) as well as decrease in the pulmonary artery pressure. The aim of this study was to evaluate the efficacy and safety of high dose streptokinase (SK) in 1 h versus low dose SK in 24 h in patients with submassive PE and RVD (high risk PE). The study included 60 patients (28 males and 32 females, mean age 45.5 ± 13.6 years) with submassive PE (positive spiral CT chest) and RVD (proved by echocardiography). Those without contraindications to SK were randomly assigned to receive either high dose (group I) or low dose (group II) of SK. Those with contraindication(s) to SK received anticoagulation (group III). Echocardiography was done before and 72 h after treatment. Right ventricular dysfunction (RVEDD, PSM, and TR) and mean pulmonary artery pressure (PAP) improved significantly 72 h after treatment in

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groups I and II, while a slight improvement in PAP was observed after treatment in group III. No significant difference was noticed between groups I and II regarding the effect of treatment on RVD or PAP. Statistically nonsignificant difference was found between groups I and II regarding the complications of SK, however a slightly higher risk of bleeding was observed in group I (high dose SK). No significant difference was found between the three groups regarding the mortality. These data suggest that SK can rapidly and safely reverse the pulmonary hypertension and RVD in contrast to anticoagulation. Both protocols of SK are equieffective in rapid reversal of RVD and pulmonary hypertension. Both protocols were safe as proved by absence of difference in mortality over anticoagulant group.

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1. Introduction

Pulmonary embolism (PE) is a common disorder associated with substantial morbidity and mortality; autopsy series have shown that PE is responsible for 15% of all in-hospital deaths.[1]

Anticoagulants remain the standard of care for venous thromboembolism (VTE); anticoagulation prevents clot propagation and allows endogenous fibrinolytic activity to dissolve existing thrombi, a process that typically occurs over several weeks or months. Thrombolytic therapy, by actively dissolving thromboembolic, offers several potential advantages over anticoagulation in the treatment of patients with VTE.[2]

Thrombolysis is an established treatment for patients with massive PE and haemodynamic instability (cardiogenic shock or persistent arterial hypotension). In contrast, the effect of thrombolytic agents on the outcome of haemodynamically stable patients who have submassive PE has been debated for decades.[3,21,22]

Registry data indicate that right ventricular dysfunction (RVD) in patients with PE is associated with an increased risk of fatal outcomes even in patients who are haemodynamically stable.[4,18,19]

The indication and rationale for thrombolysis in submassive PE remain debatable as no large-scale randomized controlled clinical trials comparing thrombolytic agents, or thrombolysis and anticoagulation to anticoagulation alone have been performed.[5,18,19,21]

The aim of this study was to compare the efficacy and safety of high dose streptokinase (SK) in 1 h versus low dose SK in 24 h in patients with submassive PE and RVD.

2. Patients and methods

Sixty patients (28 males and 32 females) with submassive PE and RVD were enrolled in the study. The mean age was 45.5 ± 13.6 years (range 22–75 years).

2.1 Inclusion criteria

(a) Proven PE by spiral CT scan of the chest. (b) Evidence of pulmonary hypertension and/or RVD (RV dysfunction) including increased right ventricular end diastolic diameter (RVEDD), paradoxical inter-ventricular septal motion (PSM), and tricuspid regurge (TR). (c) Patients age range 18–75 years. (d) Patients referred within 14 days after the onset of symptoms.

2.2. Exclusion criteria

(a) Normal echocardiographic examination (minor PE). (b) Haemodynamic instability or cardiogenic shock (massive PE). (c) Previous PE.

2.3. Protocol

Patients without contraindications to thrombolysis were randomly assigned to receive either high dose SK; 1,500,000 U over 1 h (group I; included 15 patients) or low dose SK; 250,000 U over 30 min followed by100,000 U/h for 24 h (group II; included 25 patients). Thrombolysis was followed by anticoagulant therapy (unfractionated heparin and warfarin). Those with contraindication(s) to thrombolysis received anticoagulant therapy (group III; included 20 patients).

2.4. Contraindications for thrombolysis (risk of bleeding)

Cerebrovascular accident, intracranial trauma or surgery within the last 2 months; active intracranial disease (neoplasm, aneurysm, vascular malformation); major internal bleeding within past 6 months; uncontrolled hypertension (systolic blood pressure >200 mmHg, diastolic blood pressure >110 mmHg); bleeding diathesis, coagulopathies or platelet count $<100{,}000\ mm^3$; recent major surgery, organ biopsy or labour (within 10 days); recent trauma; infective endocarditis/pericarditis; pregnancy; aortic aneurysm; hemorrhagic retinopathy; decompensated liver disease, and renal failure.[7]

2.5. Pre-treatment evaluation

This included recording of the vital signs, arterial blood gases, ECG, chest X-ray (CXR), study of the venous system of the lower limbs using Duplex ultrasound, post-contrast spiral CT of the chest, echocardiography (for measurement of PAP and evidence of RVD: RVEDD, PSM, and TR), and laboratory tests (CBC, INR, PTT, and creatinine).

2.6. Post-treatment evaluation

Seventy-two hours after treatment the following data were reevaluated: vital signs, arterial blood gases, and echocardiography (for re-measurement of PAP and detection of RVD: RVEDD, PSM, and TR).

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