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Abstract:

Background: Acute submassive pulmonary embolism (PE) with right ventricular (RV) injury and/or concomitant deep venous thrombosis can cause persistent symptoms that degrade quality of life. We tested the hypothesis that intravenous

tenecteplase would improve the probability of a favorable outcome at three months after submassive PE. Methods: Multicenter randomized double-blind, placebo controlled trial. Eligible patients were ambulatory at baseline, had image-proven acute PE, a systolic blood pressure > 90 mm Hg and RV dysfunction (abnormal echocardiography, troponin or brain natriuretic peptide). Patients received anticoagulation with low molecular weight heparin (LMWH) and either tiered-dose tenecteplase or saline in an opaque syringe. Composite favorable outcome: 5 day survival to hospital discharge without shock, intubation, or major hemorrhage (any intracranial bleed or need for surgical or medical intervention for acute anemia), and at 90 days, normal RV on resting echocardiography, 6 minute walk distance>330 m, no dyspnea at rest, and no recurrent PE or DVT. Self-perception of wellness was assessed by the SF-16, VEINES-QOL and rank on 1-10 ordinal scale. Results: 83 patients were enrolled, including 33 women, 52 Caucasians, mean age 55+/-14 years, 43 received placebo, 40 received tenecteplase, and 38 had concomittant DVT. A favorable composite outcome occurred in 17/43(40%, 95% CI: 25-56%) treated with placebo, versus 26/40 (65%, 95% CI: 48-79%) treated with tenecteplase, p=0.02 Fisher' s exact. Acute deterioration occurred in 3 patients treated with placebo: fatal PE (1), intubation (1), thrombectomy (1) and in one patient treated with tenecteplase who had a fatal intracranial hemorrhage. At three months, a nonfavorable outcome was found in 23 additional patients treated with placebo, versus 13 patients treated with tenecteplase. Assessments of wellness were consistently higher in the tenecteplase group (e.g., p=0.03 for ordinal scale rank). Conclusions: In this randomized trial, patients with submassive PE treated with LMWH and tenecteplase were more likely to have a favorable patient-oriented outcome at three months than patients treated with LMWH and saline placebo.

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