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Title: Recombinant thrombomodulin improves survival in acute exacerbation of idiopathic pulmonary fibrosis

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Body: Background: Acute exacerbations of idiopathic pulmonary fibrosis (AE-IPF) are episodes of acute respiratory worsening caused by unknown etiology with high short-term mortality. The presence of disordered coagulation and endothelial damage in AE-IPF have been reported. Recombinant human soluble thrombomodulin (rhTM) binds to thrombin to inactivate coagulation, and the thrombin-rhTM complex activates protein C to produce activated protein C. The purpose of this study is to examine the efficacy of rhTM for treating patients with AE-IPF. Methods: Patients with AE-IPF in our hospital from 2006 to 2011 were enrolled. AE-IPF was defined using the revised Japanese criteria for AE-IPF (Eur Respir J. 2010;35:821-9.). All patients received corticosteroid pulse therapy and immunosuppressant (cyclosporine 3mg/kg/day, p.o). NPPV was the first line intervention. The initial 20 patients treated without rhTM (control group) and following 20 consecutive patients treated with rhTM (0.06 mg/kg/day) for six days (rhTM group) were compared. The predictors of 3-month survival (Cox proportional-hazards model) were evaluated. Results: Baseline characteristics show age(mean:72.2), PaO_2/FiO_2(220), APACHE II(9.9), C-reactive protein(CRP)(7.1) mg/dl, KL-6(1485) U/ml. In univaliate analysis, respiratory rate, CRP, rhTM therapy were significant predictors for 3M survival. In multivaliate analysis, CRP (p=0.008,HR=1.133), rhTM therapy(p=0.015,HR=0.172) were significant predictor for 3M survival. Conclusion: We found that rhTM therapy improves 3-month survival of AE-IPF in our case control study. The results observed here support further investigation of rhTM in randomized control trials.