

European Respiratory Society Annual Congress 2013

Abstract Number: 807

Publication Number: P3760

Abstract Group: 1.4. Interventional Pulmonology

Keyword 1: Animal models **Keyword 2:** Airway management **Keyword 3:** Bronchoscopy

Title: Macro and microscopic evaluation of paclitaxel delivery in the airway with a novel endobronchial injectable drug delivery catheter

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Body: Introduction: Direct injection of an anti-cancer agent into airway malignancy to maintain airway is one of the palliative interventional options. We have previously reported a new endobronchial injection catheter through a flexible bronchoscope (Seward, K. P. et al. CHEST 2010;138:420A ,421A). Normal tissue reaction against anti-cancer agent must be evaluated in vivo prior to the human application. Aim: The purpose of the study was to assess the bronchoscopic and histopathological findings of porcine airway 1 week after injecting varying concentrations of paclitaxel (PTX). Methods: Diluted PTX was infused through the Blowfish™ Transbronchial Micro-Infusion catheter in 1 ml volume for each treatment. The animals underwent bronchoscopic evaluation prior to sacrifice on day 7. Histological findings were evaluated by according to the semi-quantitative bronchial damage scoring system. Results: PTX concentration of 0.05 mg/ml was injected into 13 sites (n=1), 0.5 mg/ml was injected into 13 sites (n=1), 2.5 mg/ml was injected into 5 sites (n=1), respectively. In the animal receiving 2.5 mg/ml, there was immediate injection reaction with whitening of the bronchial wall surrounded by hyperemic area which was subsequently covered by white yellowish necrotic tissue on day 7. Mild inflammation and minimal epithelium loss were observed in 0.05 mg/ml and 0.5 mg/ml injection group, moderate inflammation and significant epithelial loss were observed in 2.5 mg/ml animal. Conclusion: A 2.5 mg/ml PTX injection developed mucosal ulceration, while 0.05 and 0.5 mg/ml injections were well tolerated. Local tissue and systemic plasma drug concentration will be analyzed.