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Title: Rituximab in severe, treatment-refractory interstitial lung disease

Dr. Rezaur 25776 Abdullah reza.abdullah@gmail.com MD [1], Dr. Damien 25777 Ming d.ming@rbht.nhs.uk MD [1], Dr. Gregory 25778 Keir g.keir@rbht.nhs.uk MD [1], Dr. Toby 25779 Maher t.maher@rbht.nhs.uk MD [1], Prof. Athol 25780 Wells Athol.Wells@rbht.nhs.uk MD [1] and Dr. Elisabetta 25838 Renzoni E.Renzoni@rbht.nhs.uk MD [1]. [1] Interstitial Lung Disease Unit, Royal Brompton Hospital, London, United Kingdom .

Body: Background In a subgroup of patients with severe interstitial lung disease (ILD) progressing despite conventional immunosuppression, rituximab, a B cell-depleting monoclonal antibody, may offer an effective rescue therapy. Methods Retrospective assessment of 50 patients with severe, progressive ILD (34 with connective tissue disease-associated ILD, 7 with fibrotic hypersensitivity pneumonitis, 3 with likely drug-induced ILD, the rest with miscellaneous ILD patterns, excluding idiopathic pulmonary fibrosis) treated with rituximab between 2010 and 2012. At the time of rituximab treatment, mean DLco was 25.5 % (±9.9%), and FVC was 49.1% (±17.6%). Change in pulmonary function tests compared to pre-rituximab levels, was assessed at six to twelve months post-treatment. Changes in lung function before and after treatment were analysed by Wilcoxon signed rank test. Results In contrast with a median decline in forced vital capacity (FVC) and diffusing capacity for carbon monoxide (DLco) of 14.6% and 18.8% respectively in the six to twelve months prior to rituximab, analysis of paired pulmonary function data revealed a median improvement in FVC of 5.7% ($p<0.01$) and stability of DLco ($p<0.01$) in the six to twelve months following rituximab treatment. Two patients developed serious infections (pneumonia) requiring hospitalisation following rituximab, and ten patients died, all from progression of underlying ILD, a median of 5.1 months after treatment. Conclusions In a subgroup of patients with severe, progressive ILD unresponsive to conventional immunosuppression, rituximab may offer a safe and effective therapeutic intervention. Future prospective, controlled trials are warranted to validate these findings.