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Title: Efficacy of rituximab in patients with connective tissue disease associated interstitial lung disease: Preliminary results in safety and clinical response

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Body: Objectives: We present safety and clinical outcomes of Rituximab (RTX) in connective tissue diseases-associated interstitial lung disease (CTD-ILD) in a real-life clinical setting. Methods: Efficacy was assessed by lung function tests (LFT) and high-resolution computed tomography (HRCT). ILD exacerbations and safety were assessed. Results: 14 patients with CTD-ILD (29% rheumatoid arthritis, 21% Sjögren, 21% unclassifiable CTD, 14% systemic sclerosis and 14% myopathies) received 4000mg (2000 – 6000) RTX (observation period 161 patient-year). ILD patterns were: 57% usual interstitial pneumonia, 21% unclassifiable ILD, 7% nonspecific interstitial pneumonia, 7% cryptogenic organizing pneumonia and 7% lymphoid interstitial pneumonia. At baseline, IgG levels and leukocyte subset counts were within normal range, with reduced numbers of unswitched memory B cells. Incidence infection rate during RTX therapy was 4.35/100 patient-month (p/m) with one case severe. There was 1 death, due to neutropenia with a disseminated fungal infection. LFT available in 12 patients showed an overall improvement in FVC (85%±19 vs. 73%±18) and DLCO (58%±18 vs. 45%±19). Radiographic progression could be evaluated in 6 patients, with 5 stabilized and 1 improved. ILD incidence relapse rate during RTX therapy was 0.745/100 p/m compared to 5.56/100 p/m in the pre-treatment period. Conclusions: Our preliminary data indicate that RTX is safe and shows a low exacerbation rate. Although optimal outcome measures in the short term are difficult to establish, we could confirm disease stabilization in most patients.