European Respiratory Society
Annual Congress 2012

Abstract Number: 4877

Publication Number: P694

Abstract Group: 1.5. Diffuse Parenchymal Lung Disease

Keyword 1: Idiopathic pulmonary fibrosis **Keyword 2:** Anti-inflammatory **Keyword 3:** No keyword

Title: A prosprective study on the safety, tolerability and efficacy of pirfinidone in the treatment of idiopathic pulmonary fibrosis and fibrotic NSIP

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Body: Prospective study conducted on 39 patients with IPF and fibrotic NSIP on patients visiting at Bombay Hospital, Mumbai. Out of 39,9 patients failed to follow up while 9 patients expired on the treatment. Drug had to be stopped in one patient due to reaction. 13% of the patients had a diagnosis proven on surgical lung biopsy. The remaining had their diagnosis confirmed on HRCT, of which 74.4% revelead honey combing and 28% revealed ground-glass opacities. The mean FVC at baseline has been 1.78lts (57% predicted SD 19%) and 1.57(61% predicted SD 11.53) at 6 months. The mean corrected DLCO at baseline was 38.29% 39.58% at 6 months. The mean oxygen saturation at baseline 95.38% and 95.82% at 6 months. The 6 min walk test was almost the same at the end of 6 months too (329 vs 331meters). Though patients dropped to a mean saturation of 84.53% post walk at baseline, this did not significantly change 6 months either. tThe drug has been quite well tolerated too. None of the patients have elevated liver enzymes and only one patient developed skin rash. GI discomfort and loss of appetite were other side effects that were noted. The average dose of pirfenidone taken during this period was 1082.05 mg/day and the maximum dose administered has been 1800mg/day. Pirfinidone is the only approved drug for IPF currently available in the world. Considering its previous efficacy documented in slowing the decline in FVC, we thought it appropriate to do this observational study not just on IPF but also on fibrotic diseases to assess its tolerability over a period of time and its potential efficacy in these conditions.