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Title: Pirfenidone in idiopathic pulmonary fibrosis (IPF): Early Spanish experience with the European Named patient program (NPP)

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Body: The NPP allowed access to pirfenidone before commercialisation for the same indications with local medical agencies consent. Aim: To describe the early Spanish experience of patients with IPF treated with pirfenidone included in NPP. Methods: Pulmonologists who had already prescribed pirfenidone under NPP were invited to participate. IPF was diagnosed following the 2011 ATS/ERS/JRS/ALAT criteria. Baseline data registered were: symptoms, demographic, pulmonary function test, FVC (ml and % predicted), DLCO (% predicted), distance, SpO2 initial and final in six minutes walking test (6MWT), radiological and histological data. Related with pirfenidone treatment, side effects, achieved dose and treatment interruption data were collected. Follow up included pulmonary function test were assessed. Results: 86 patients (62 men) were included. The basal functional data were (mean±SD): FVC 2300±870 ml, (70±19%); DLCO 45±19 %; 6MWT distance 413 ± 124 m, SpO2 initial 94± 3% and 86±7 % final. 64 patients were diagnosed by clinical radiological criteria and in 24 a surgical biopsy was performed. 80/86 patients get pirfenidone 2403 mg daily. Treatment was withdrawal in 12/86 patients due to side effects, another 27 patients ongoing on treatment reported mild to moderate side effects. Gastrointestinal events in 35/86 and photo-sensitivity in 11/86 were the most commonly reported. One patient died due acute IPF exacerbation. Amongst subjects who had repeated pulmonary function testing (n=20), there was no significant decline in FVC and DLCO between baseline and follow up. Conclusion: The safety profile in the Spanish NPP patients appears consistent with recent published data.