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Title: Pirfenidone, proton pump inhibitor, N acetyl cysteine (PINPOINT) therapy for IPF: Tolerance and safety profile among Indian patients

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Body: Rationale: To our knowledge there are no data of PIrfeNidone, PrOton pump Inhibitor, N acetyl cysteine Therapy(PINPOINT) in IPF. We retrospectively examined the safety & tolerability of PINPOINT in IPF-UIP. Methods: 40 consecutive patients with IPF-UIP administered PINPOINT, Pirfenidone 200 mg three times day & titrated to 400 mg three times day over 2 to 4 weeks, a proton pump inhibitor & N-acetyl cysteine 1800 mg/day. Baseline liver function tests were performed. Lung function & 6MWT were possible in 25 patients. Patients were followed at 2 weeks, then monthly/quarterly. Prednisolone was administered 10 mg/day & reduced on follow up based on clinical assessment. Four newly diagnosed patients were given only PINPOINT. Results: Baseline mean spO2 at rest was 95% & mean FVC 1.30 litres (55% predicted). Baseline liver function were normal in all patients. Mean lowest spO2 on 6 minute walk test was 90%. There was no significant increase in liver enzymes at follow up. 17 patients had pulmonary hypertension on 2D Echo. Mean duration of follow up was 241 days. In 25 patients, Pirfenidone could be increased to 1200 mg/day. Dose could not be increased to 1200 mg/day in 11 patients due to gastrointestinal side effects (nausea/vomiting 10 patients, loose motions - one patient). Pirfenidone was stopped in five patients because of skin itching & rash (4 patients 600mg/day, 1 patient 1200 mg/day). 5 patients continued to take Pirfenidone despite skin itching (no skin discoloration) after counseling about side effects & took symptomatic treatment. 5 patients expired during this period. Conclusion: PINPOINT therapy appears to be well tolerated in patients with IPF-UIP.