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LETTER TO THE EDITOR

Successful and practical pirfenidone desensitization

Şeyma ÖZDEN[1](ID)
Fatma Merve TEPETAM[1](ID)
Dildar DUMAN[2](ID)
Fatma TERZİOĞLU ŞAHİN[2](ID)

[1] Clinic of Immunology and Allergy, University of Health Sciences, Süreyyapasa Chest Diseases and Thoracic Surgery Training and Research Hospital, İstanbul, Türkiye
[2] Clinic of Chest Diseases, University of Health Sciences, Süreyyapasa Chest Diseases and Thoracic Surgery Training and Research Hospital, İstanbul, Türkiye

Dear Editor,

Idiopathic pulmonary fibrosis (IPF) is a long-term and progressively worsening interstitial lung disorder with an undefined etiology and a poor prognosis. It mainly affects middle-aged and older individuals. Pirfenidone is an oral anti-fibrotic and anti-inflammatory agent that was previously approved in Europe in 2011 for the treatment of IPF and in the USA in 2014 (1). In the 2015 update to the American Thoracic Society/European Respiratory Society/Japanese Respiratory Society/Latin American Thoracic Association treatment guidelines, pirfenidone was listed as one of the only two novel agents conditionally recommended for the treatment of IPF (2). A wide range of cutaneous adverse reactions associated with pirfenidone use have been described in the literature, including maculopapular rashes, toxidermias, and drug-induced lupus. The most frequently reported reactions are photosensitivity reactions, both phototoxic and photoallergic in nature. In a case series examining skin reactions, the mean time between the initiation of pirfenidone and the onset of cutaneous manifestations was reported to be 5.5 months (3,4). When we reviewed the literature on pirfenidone desensitization, we found only two case reports. In the first case, the total desensitization process lasted 236 days, requiring the patient to visit the hospital frequently, which was considered impractical (5). In the other case report, the desensitization protocols applied on days 0 and 42 consisted of fewer than five steps, making them unsuitable for desensitization (4). Based on this, we wanted to share our own pirfenidone desensitization protocol, which is highly practical for clinical use and has been successfully implemented.

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Address for Correspondence
Dr. Fatma Merve TEPETAM
Clinic of Immunology and Allergy, University of Health Sciences, Süreyyapasa Chest Diseases and Thoracic Surgery Training and Research Hospital
İSTANBUL-TÜRKİYE
e-mail: fatmamervealan@hotmail.com

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An 82-year-old male patient was started on pirfenidone 600 mg tb (Pirfect®, Nobel İlaç, Türkiye) with a diagnosis of IPF by pulmonology. The patient used the drug without any problems for the first two days, but on the third day, he started to report urticarial plaques on his face, upper and lower extremities approximately one hour after taking the drug. The patient had no medical history of atopic diseases such as allergic rhinitis, asthma, atopic dermatitis or urticaria. However, he stated that he had similar complaints 30 minutes after taking naproxen tb about 10 years ago. However, it was confirmed that he was not taking any other medication concurrently with pirfenidone. He was referred to the pulmonology department, and it was stated that he should definitely use pirfenidone. Skin prick tests with respiratory and food allergens revealed no sensitization. Skin prick test with pirfenidone was negative.

Oral desensitization was administered without premedication by taking necessary precautions for the patient, starting at a dose of 5 mg and increasing every 15 minutes for a total of 600 mg in 8-steps. For the following six days, the patient continued to use pirfenidone 600 mg at home. On the eighth day, 9-step desensitization with 1200 mg pirfenidone was performed as the dose was to be increased. The patient was observed for two hours after desensitization, and no reaction developed. Again, on the following days, the patient continued to take pirfenidone 1200 mg at home. On the 15th day, 6-step desensitization was performed to reach a target dose of 1800 mg, and the patient was observed for two hours (Table 1). No allergic reaction developed during or after the procedure. The patient continued to use 1800 mg pirfenidone in maintenance treatment without any problems. Since this patient was of advanced age

Table 1. Pirfenidone desensitization protocol

Solution A: ¼ tb (150 mg) pirfenidone (content of tablet) + 15 cc 0.9% isotonic sodium chloride (Concentration: 10 mg/mL)

Day 1	Step 1	Solution A	0.5 cc (5 mg)
	Step 2	Solution A	1 cc (10 mg)
	Step 3	Solution A	1.5 cc (15 mg)
	Step 4	Solution A	2 cc (20 mg)
	Step 5	Solution A	4 cc (40 mg)
	Step 6	Solution A	6 cc (60) mg
	Step 7	150 mg tablet	¼ tb (150 mg)
	Step 8	300 mg tablet	½ tb (300 mg)
Day 8	Step 1	Solution A	0.5 cc (5 mg)
	Step 2	Solution A	1 cc (10 mg)
	Step 3	Solution A	1.5 cc (15 mg)
	Step 4	Solution A	2 cc (20 mg)
	Step 5	Solution A	4 cc (40 mg)
	Step 6	Solution A	6 cc (60) mg
	Step 7	150 mg tablet	¼ tb (150 mg)
	Step 8	300 mg tablet	½ tb (300 mg)
	Step 9	600 mg tablet	1 tb (600 mg)
Day 15	Step 1	75 mg tb	1/8 tb (75 mg)
	Step 2	150 mg tb	¼ tb (150 mg)
	Step 3	225 mg tb	¼+1/8 tb (225 mg)
	Step 4	300 mg tb	½ tb (300 mg)
	Step 5	450 mg tb	½+¼ tb (450 mg)
	Step 6	600 mg tb	1 tb (600 mg)

Day 2-3-4-5-6 and 7: 600 mg tb (1 tb) at home; day 9-10-11-12-13 and 14: 1200 mg (2 tb) at home; day 16 and the following days; 1800 mg (3 tb) at home.

(82 years) and his body mass index was at the lower limit of normal (21.8 kg/m^2) and studies have shown that low dose pirfenidone has beneficial effects on survival and decreased pulmonary function in real world practice, it was decided by pulmonology that the maintenance dose should be 1800 mg (6).

Patients with a history of pirfenidone hypersensitivity reaction will be able to receive this treatment safely and effectively with our proposed desensitization protocol.

Peer-review: Externally peer-reviewed.

CONFLICT of INTEREST

The authors declare that they have no conflict of interest.

AUTHORSHIP CONTRIBUTIONS

Concept/Design: FMT, ŞÖ, FTŞ

Analysis/Interpretation: DD, ŞÇ, FMT

Data Acquisition: All of authors

Writing: All of authors

Clinical Revision: All of authors

Final Approval: All of authors

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