EFFECTIVENESS, SAFETY, AND MONITORING OF PIRFENIDONE AND NINTEDANIB IN IDIOPATHIC PULMONARY FIBROSIS

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5PSQ_055

Background and Importance

Idiopathic pulmonary fibrosis (IPF) is a rare disease with an estimated incidence of between 46 and 74 per 100,000 inhabitants.

Pirfenidone and nintedanib are funded for mild-moderate IPF with a lung transplant application or for non-candidates with a forced expiratory volume in 1 second (FEV1) / forced vital capacity (FVC) ratio >0.8 (pirfenidone) and >0.7 (nintedanib) and a predicted diffusing capacity of the lung for carbon monoxide (DLCO) of 35-90%. The therapeutic positioning report (TPR) specifies that an evaluation should be performed at 6-12 months to assess lack of response: a reduction in FVC >10% or DLCO ≥15% over an interannual period or less, in which case treatment should be discontinued, and other therapeutic alternatives considered.

Aim and Objectives

The objective is to compare effectiveness and safety between both antifibrotic agents, adherence to the TPR, and alignment with clinical follow-up.

Material and Methods

Retrospective study-decembre 2023

Data collected included: sex, age, baseline, 6-12 months, and current FVC and DLCO, responder status, adverse events (AEs), treatment discontinuations, reasons for discontinuation, and sequencing.

For the effectiveness analysis, patients with a treatment duration ≤6 months were excluded.

Data collection: Prisma® outpatient module and electronic medical record. In the statistical analysis performed, quantitative variables were described in frequency tables and central tendency measures, and categorical variables were analyzed using the Chi-square test.

Results

31 patients were recruited (54.84% women, mean age 71 ± 9.53 years).

1 patient with pirfenidone and 1 with nintedanib did not meet the TPR initiation criteria.

The effectiveness analysis included 29 patients, and the safety analysis included 31. 1 and 5 patients continuing on pirfenidone and nintedanib, respectively, showed reductions in FVC and/or DLCO exceeding the limits described in the TPR.

	PIRFENIDONE	NINTEDANIB	PIRFE → ← NINTE
Patients	5	21	5
The percentage of responders	70% (95% CI 38.7% – 89.2%) p=0,2	45.8% (95% CI 28.9% – 62.9%) p=0,2	
AEs	57% (95% CI 40.1% – 75.2%) p=0,02	85% (95% CI 68.5% – 94.3%) p=0,02	
Discontinuations (patients)	2 (1 due to AEs and 1 death)	7 (5 due to AEs, 1 due to death, and 1 due to progression)	

Conclusion and Relevance

In our experience, there are no statistically significant differences in the percentage of responders between the two antifibrotic agents, although nintedanib presents a significantly higher incidence of AEs. Additionally, some patients did not meet the initiation and continuation criteria of the TPR. This implies economic expenditure without apparent benefit and may even cause avoidable toxicity, highlighting the importance of thorough review of these patients by pulmonology and pharmacy.

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