OPINION

In-depth effectiveness and safety of nintedanib in treating idiopathic pulmonary fibrosis: An Indian single-center observational study

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ABSTRACT

Numerous clinical trials have proven nintedanib's efficacy and safety in the treatment of Idiopathic Pulmonary Fibrosis (IPF). The purpose of this study is to evaluate nintedanib's effectiveness and safety in Indian patients with IPF.

Key Words: *Idiopathic Pulmonary Fibrosis*

OPINION

Idiopathic Pulmonary Fibrosis (IPF), whose prevalence ranges from 2 people to 9 people per 100,000 people, is an Interstitial Lung Disease (ILD) that is chronic, progressive, has no known cause, and is characterized by a sharp loss in lung function. Those who are exposed to specific risk factors are more likely to develop the condition, which primarily affects the elderly. With a median survival span of only two to three years, IPF has a terrible prognosis. Forced Vital Capacity (FVC) predicted, Diffusing Capacity of the Lung for Carbon Monoxide (DLCO), 6-Min Walk Distance (6-MWD), and clinical and radiographic alterations are used to track the progression of IPF. Gender, age, and two physiological indicators make up the "GAP index," which aids in predicting the prognosis of IPF patients. In IPF, treatment aims to lessen symptoms and slow the disease's progression. While there is no medication that "cures" IPF, antacids can help with reflux symptoms, and pirfenidone and nintedanib, two antifibrotics, can slow the disease's progression. The vascular endothelial growth factor receptor, the fibroblast growth factor receptor, and the platelet-derived growth factor receptor are all powerfully inhibited by the small molecule tyrosine kinase inhibitor nintedanib. One phase II trial and two identical phases III studies were used to evaluate the effectiveness and safety of nintedanib in IPF. The trials showed that nintedanib considerably decreased the annual rate of decline in FVC, which is how the disease progressed more slowly as a result. Additionally, it may lower the frequency of acute exacerbations and enhance life quality for those who are health-related. Although the subgroup analyses of INPULSIS demonstrated that nintedanib is normally helpful in a wide range of IPF patients, there is a dearth of published research on its practical application.

The efficacy of nintedanib on IPF patients in clinical practice was recently studied in India, but the sample size was relatively small. To evaluate the effectiveness and safety of nintedanib in actual clinical settings in India, the current study was conceptualized in bigger cohorts of IPF patients. Retrospective data analysis was done on IPF patients' clinical records who visited the tertiary pulmonary care facility in North India between June 2016 and December 2019. After deleting patient identifiable information, the data were converted to digital form and entered into a case record form. For the analysis, the complete patient records were consulted. The investigation comprised patients who were given nintedanib after being diagnosed with IPF according to the European Respiratory Society/American Thoracic Society guidelines. Patients without any subsequent appointments were not included. Since patients were being followed up in the center's ILD Clinic, recruitment and follow-up were conducted by the protocol in place, whereby a diagnosis is made following a multidisciplinary discussion, and all patients are monitored every 8 weeks–12 weeks for routine procedures and a lung function assessment. For the study of patient data, institutional ethics committee approval was obtained. Two doses of nintedanib were used to treat the IPF patients. Based on clinical practice (tolerance and liver functions) used for the treatment of IPF patients in India, the 100 mg and 150 mg doses of nintedanib were chosen. In our clinical practice, we start nintedanib treatment at 100 mg BID for patients with low body weight instead of the standard strategy of starting at 150 mg BID and reducing it to 100 mg BID if necessary. If the 100 mg dose is well tolerated, we then increase the dose to 150 mg BID at the first follow-up. If the 150 mg BID dose is not tolerated, we return to the 100 mg BID dose. Acute exacerbations were defined as episodes of acutely deteriorating dyspnea and lung function without a known reason.

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Before beginning nintedanib medication, 72 patients had a history of acute exacerbations. During the trial, 48 individuals reported acute exacerbations. Only mild to moderate exacerbations that have been treated in the outpatient setting are being evaluated. The repeat evaluation window was 4 weeks to 8 weeks, thus they could only be done then. Increased oxygen demand and the need for antibiotics and steroids temporarily were caused by these exacerbations. The study offers information about the IPF patients encountered in clinical settings in India. Clinical trials offer a higher level of proof, but their participants are more carefully chosen, and they might not include all the patients who will ultimately receive the medication in clinical practice. Thus, real-world evidence closes this gap and offers information on a drug's safety and effectiveness across a larger patient population. The results of the current trial showed that nintedanib has the potential to help IPF patients by lowering their DLCO and FVC percentages and enhancing their 6-MWD. Only 6 patients reportedly experienced moderate adverse effects that were treated by reducing the dose. This demonstrated how well nintedanib was tolerated by IPF patients. The patients in our trial, in general, had a lower average age, a lower FVC predicted, and comparable frequencies frequencies of concomitant conditions when compared to a few previous real-world studies using nintedanib in IPF conducted around the world (except for diabetes, which was higher in Indian patients). In comparison to other investigations, DLCO was discovered to be practically identical. Although males outnumbered females in our study as well, the proportion of males was lower than in the INPULSIS trials and other real-world investigations. Despite minor variations in patient characteristics, it is significant to note that our results were broadly consistent with those of other real-world studies: nintedanib appears to stabilize lung function in IPF in the majority of patients and is well tolerated. The study offers the most extensive data from India regarding nintedanib's actual use in IPF. According to the findings, patients from India are often younger than those from the West or Japan. At the time of diagnosis, FVC predictions for Indian patients often are worse. This may be due to a delay in receiving care and/or in getting an accurate diagnosis, necessitating more public and medical professional knowledge of ILDs. Our findings confirm that nintedanib slows the course of IPF and is typically well tolerated, findings that have been made in clinical trials and other real-world research.