Real-world Long-term Experience with Antifibrotic Treatment

This is an interesting study done in Turkey by a group of investigators led by Nacy et al. It's a retrospective study to understand the long-term effects of the anti-fibrotic treatment in patients with idiopathic pulmonary fibrosis in the real world. So after the anti-fibrotic drug became available for clinicians to use, the long-term observational study in the real world is what this group of investigators did in Turkey.

It was an interesting study to say what really occurs in the real world, compared to all the clinical trials that have been done in multicenter, multinational clinical trials. So in this particular study, patients with well-defined idiopathic pulmonary fibrosis as defined by the community physicians receiving pirfenidone or nintedanib, the two anti-fibrotic treatments that has been approved for patients with idiopathic pulmonary fibrosis in routine clinical practice over a period of four-years-time was essentially studied by this group of investigators, and report their observational study in this ERS session.

So what they found really is, that in the real world, the longterm observation study showed that both pirfenidone and nintedanib demonstrated the acceptable safety and efficacy as was demonstrated in the original phase three clinical trials. And also, both agents were equally effective in reducing the rate of the decline of the forced vital capacity, as well as the deficient capacity and the rate of acute exacerbation and overall survival over a period of three years' time.

While this data is reassuring that the original data, the phase three clinical trials were done in regional centers, well established tertiary centers of excellence for interstitial lung disease, but in the real world, where the community physicians are diagnosing patients with idiopathic pulmonary fibrosis. So this is reiterating and reassuring that the pirfenidone and nintedanib, when used in the real world experience, the efficacy and the safety is very similar to what was observed in the clinical trials. So basically, it's really assuring and reiterating what has been already established in clinical trials. So therefore, it would be an appropriate security blanket if you will, for both patients and physicians to be using the anti-fibrotic treatment routinely in clinical practice for patients with idiopathic pulmonary fibrosis.

So this study actually is a retrospective observational study. While it is reassuring, prospective observational studies that collect similar well-defined data over time are needed to answer some more residual questions on long-term anti-fibrotic treatment and outcomes in idiopathic pulmonary fibrosis.

Well, this particular study assessed the effectiveness of pirfenidone in idiopathic pulmonary fibrosis in Germany or in Europe, long-term, real world data from the European IPF registry. So what the study really looked into is the really long-term effects or many years of patients who have been diagnosed with idiopathic pulmonary fibrosis from the data gathered at the European IPF registry from patients from the university of Giessen and Marburg Lung Center. 122 patients were available to assess the long-term effects of the pirfenidone. And what they showed really was what is already known based on the clinical trial, and they report the effectiveness of pirfenidone in the real world, idiopathic pulmonary fibrosis cohort, with the outcome data extending up to nine years.

And what the studies before had been looking into the data only for about a year plus or so, but going up to nine years is an interesting long term data. And so they demonstrated a continued positive effect of the pirfenidone treatment on the rate of the way, how the forced vital capacity declines. Remember, the pirfenidone slows down the disease progression, it doesn't really stop or improves. So what we follow in real practice for patients with idiopathic pulmonary fibrosis, what's the rate of the slope of their decline? And so the pirfenidone, what it is known to do? It slows down the rate of the forced vital capacity decline over a period of a year or a year and a half in the phase three clinical trial.

Now, this long-term study is reassuring that the positive effect of the decrease in the rate of the forced vital capacity decline, as well as other functional variables in the deficient capacity and some in the six-minute-walk distance, and the dyspnea scale all seem to go in the right direction over a period of several years up to nine years-time. So this is another reassuring database that pirfenidone can be used safely, because there was no concerns about the safety and the efficacy was reassured. And that would imply that it's okay to continue the treatment with pirfenidone for a longer term, as long as the patients continue to tolerate them, and indeed they did.

And also, the data suggested that a more restrictive disease by definition of the fourth world capacity, less than 80% predicted at the time of the initiation are the ones that seems to profit more, or they're the rate of decline seem to be slowed down in the diseased patient population who had the forced vital capacity less than 80% predicted at baseline.

So it's an interesting, useful study. Long-term, real world data from the European IPF Registry. And so what it means in the real practice is to go ahead and continue to use the pirfenidone as long as they're tolerating, and the rate of the forced vital capacity decline continues. So that's an interesting, useful study.