SSc-ILD: Anti-acid Therapy Treatment

SSc-ILD is systemic sclerosis associated interstitial lung disease. So as we all know, there was a prospective randomized clinical trial, first large randomized clinical trial in patients with systemic sclerosis associated interstitial lung disease to determine the safety and the efficacy of an anti-fibrotic treatment with Nintedanib.

This particular study is a post-doc analysis of the primary data that was gathered in the census clinical trial and the primary to those data have been published in the New England Journal of Medicine last year. So while the primary data clearly showed that the rate of the forced vital capacity declined in the patients with systemic sclerosis associated interstitial lung disease, receiving Nintedanib, the rate of decline slowed down.

An important question came to the investigator's mind. Well, what if there is a concomitant treatment with antacids because antacids have been shown in patients with idiopathic pulmonary fibrosis, at least that might also slow down the disease progression because patients with systemic sclerosis, interstitial lung disease and patients with systemic sclerosis do have increased prevalence and incidence of acid gastroesophageal reflux.

The important aspect of the antacid came into the investigator's mind to assess the role of the antacid treatment as a post-doc analysis. So what did they did was they took the patients who were receiving antacid treatment at baseline, and those patients who were not receiving antacid treatment. Because of the nature of the systemic sclerosis ILD, vast majority of the patients were receiving antacid treatment.

But the important part of this post-doc analysis is, does it make a difference in terms of the heterogeneity or if there is any difference of the patients receiving antacid treatment in terms of the efficacy of Nintedanib? So looking at many variables of the usual outcome measures that we assess for a response, such as forced vital capacity, whether it was an absolute measurement or percent predicted.

The bottom line of this post-doc study showed that there was really no differences in the patients who were receiving antacid treatment, versus patients who were not receiving antacid treatment at the baseline. So the data was captured at the baseline. So we know how many people took the antacid at baseline, but what we really don't know is the long-term, whether they were actually taking the antacid treatment and how many patients of their patients really had abnormal acid reflux.

There is so much variables that are not known in this particular post-doc analysis. But the bottom line of this post-doc analysis is that at least the patients who were taking antacids at baseline and assuming that they were continuing to take the antacids during the study period of time, the rate of the forced vital capacity declined by patients or by Nintedanib, did not seem to make a difference.

There was no difference between the two group. So that said, this is not necessarily a negative or a positive study, that it warrants that studies need to be done more effectively in a prospective design, looking into the issue of antacid treatment.

For example, if we design a prospective study, we will want to know how many of these patients really had abnormal acid, by doing a 24 hour pH monitoring? How many of these patients were following conservative measures to decrease reflux? So all of those factors were not taken into consideration in this study, which was not aimed to test that hypothesis.

What it warrants, at least to me, that there is an interesting data base and would warrant further studies focusing on the gastroesophageal reflux in this patient population. The issue here is simple, whether this study shows or another study shows positive or negative, unfortunately, patients with systemic sclerosis all have gastroesophageal reflux and esophageal motility problem.

It is a given that they do have problems with their reflux and esophageal functional status. So virtually, therefore patients are used to having gastroesophageal reflux symptoms and the vast majority of the patients will need to be on the treatment with antacids because they are symptomatic.

I don't think that we can take away the antacid treatment because they are symptomatic. So that's the take home would be that yes, they will need to be on it because they do have gastroesophageal reflux problems and they will have to pay attention to conservative measures.

But in terms of the efficacy of the lung function deterioration, then one would need to assess it in a more prospective design manner to assess whether the patients who were receiving appropriate antacid treatment does make a difference in terms of their combination therapy for their underlying fibrotic lung disease.