

SPEAKER 1: We now have available for our review, two papers that have been published looking at this liposomal suspension formulation of amikacin for use in NTM infections. The first looking at, a combination of Mycobacterium Avium Complex patients, plus Mycobacterium abscesses patients. And then the second, simply looking at Mycobacterium Avium infected patients.

The study design in both of those papers was quite similar. And it specifically looked at patients who were defined as having refractory disease and that refractive disease definition was again, six months of positive cultures despite multidrug antibiotic regimens that were advocated for these microbacterial infections. And again, in both of those studies it was refractory disease populations. And in both of those studies, the liposomal almost suspension amikacin drug delivery was added to the existing background goal-based therapy. And the patients were then followed with monthly sputum cultures, to assess whether, from the baseline initiation of study, they had a beneficial outcome and that beneficial outcome was assessed by sputum cultures and was defined by the conversion of cultures from sputum culture positive state to sputum culture negative state.

And what both of the studies revealed was, an improved conversion rate in the amikacin suspension treated population compared with the background population with goal based therapy alone. And, it was a roughly 30% improvement in conversion rate in the treated population with the liposomal amikacin suspension over the background drug therapy population. So that, in the use of this inhaled amikacin preparation, we appear to have a clear utility over standard background treatment and in an important and interesting population, which is, these are, if you will, the tough nut, refractory disease population. Those who, despite appropriate institution of therapy, did not have conversion. It included patients with more substantial bronchiectasis and it also importantly included patients with cavitary disease, who also had improvement in their culture conversion rates. So that this appears to be an added tool that has clear added utility over the background treatment regimen and again, that was oral based therapy, following the consensus guidelines.