

I invite Dr. Guncha to speak about the addition of bicalomethazone propionate inhalation to CTRT.

Good afternoon everyone.

Thank you for having me here.

I am going to be talking on the addition of bicalomethazone propionate inhalation to radical radiation in patients locally advanced to NSCLC.

This was a randomized control phase 2 open label trial conducted in China and was presented in SMO 2024 this year.

So we all know that thoracic radiation has a comprehensive role in the treatment of NSCLC

and radiation induced lung injury is a serious long term complication but it has limited treatment options.

They have analyzed and said that around 30% of the patients with lung or breast cancer

who are receiving radical radiation to the thorax may present with radiation pneumonitis.

The mechanisms however are poorly understood.

The purpose of this study was to explore whether the inhalation of corticosteroids during curative

radiation can reduce the incidence of radiation induced pneumonitis.

So these are the various criteria that we use for grading the radiation pneumonitis in

the clinics by the CTCA and the RTOG.

Grade 1 and grade 2 are asymptomatic or mildly symptomatic which can be managed with simple medical interventions.

However, grade 3 will be severe symptoms wherein oxygen inhalation or steroids will be used

and grade 4 will be life threatening complications or continuous oxygen requirement with cystic ventilation is required.

These are the dose constraints that we usually follow in the clinics wherein the dose to

the lungs V20 is kept usually less than 35 to 40% which has a rate of symptomatic pneumonitis

of around 20% at the end of 5 years.

So coming to the present study this was a phase 2 single center open label randomized

control trial wherein patients with histologically confirmed unresectable stage 3A or 3B.

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CTCA and this was used.

The primary end point here was the incidence of radiation pneumonitis and this steroid

then wrote the grading system that they used uh, whether it was genealogical by genealogical

of the NIKETED squared and 0.89ase and the secondary endpoints were over our response disease control rates, progression free survival, OS and toxicities. So in both the groups the population was well balanced in terms of gender age. The histology was

also adenocarcinomas in more than 60% of the patients in both the arms and stage 3B was around 80 to 25% in both the arms. Around 50-50 of the patients received either concurrent CTRT or sequential chemo radiation. So the results of the study said that there is reduced incidence of radiation pneumonitis by inhaling corticosteroids during radiotherapy and a particularly significant decrease in severe that is more than or equal to grade 3 radiation pneumonitis. Here we can see that 52% versus 35% of the patients in the prevention arm had any kind of radiation pneumonitis and grade 3 or more was seen in 12% versus 28.2% here the values 53 and 34 are out of the ones who actually had any kind of radiation pneumonitis but the overall cohort had 12% in the corticosteroid group and 28% in the control group. There was no effect on the therapeutic efficacy of radiation as far as the overall response rate and the disease control rates were concerned and there was also no effect on the overall survival in the cohorts. When we came to the safety assessment the fasting blood glucose levels of patients had increased in both the groups however more so with the corticosteroids significantly higher but this would probably have an implication and especially in patients who have a history of diabetes where the effect would be more pronounced. As such there were no significant differences in the evidence in incidence of hematologic toxicities. So when we see the incidence of grade 3 and more pneumonitis across the various trials that have come up in the past are more than or more or less around 5 to 10% is the incidence of grade 3 or more radiation pneumonitis. This present study had a little bit higher incidence but then again it was around 12% with corticosteroids. Some other agents that have been used for the prevention or we can say the treatment of radiation pneumonitis are perfinidone wherein concurrent with chemo radiation and after that for a period of six months this is a well tolerated drug with the potential to reduce the radiation induced pneumonitis and another is ninted and along with the incidence of radiation on the on the other side of the patient. So the case is that the addition of the inhaled corticosteroids to radiation significantly reduced the incidence of radiation pneumonitis in patients with an SCLC. All grade radiation pneumonitis was 35% versus 52% and the incidence of more than or equal to grade 3 radiation pneumonitis was 12% versus 28% in the control group. It does not compromise the efficacy of radiation and however the results the authors have warranted a further confirmation in for phase 3 clinical studies. Thank you.