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Surgery versus radiotherapy after induction therapy with serplulimab combined with chemotherapy for unresectable stage IIIB-IIIC non-small cell lung cancer: A randomized controlled, open-label, phase II trial

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Background

Chemoradiation followed by durvalumab is recommended for unresectable stage III non-small cell lung cancer (NSCLC) based on the PACIFIC trial. While the role of surgery remains controversial in this population.

Methods

Patients with unresectable stage IIIB-IIIC NSCLC were enrolled to receive 4 cycles (q21d) of serplulimab and platinum-based doublet chemotherapy. After the induction therapy, those with resectable disease were randomized to receive surgery or radiotherapy in a ratio of 1:1, and those with unresectable disease after induction therapy were then treated by oncologists. Primary endpoint was event-free survival (EFS). Secondary endpoints included objective response rate (ORR), major pathologic response (MPR), overall survival (OS), R0 rate of resection, and severe adverse event (SAE) rate.

Results

One hundred patients were enrolled, and the median follow-up time was 20.3 months by the data cutoff date (April 28, 2025). Sixty-six and 34 patients were diagnosed with stage IIIB and IIIC disease, respectively. Fifty patients were randomly assigned to either the surgery group (n = 23) or the radiotherapy group (n = 27). The percentage of squamous carcinomas, adenocarcinomas, and NSCLC not otherwise specified were 70.0%, 16.0%, and 14.0%, respectively. In the entire enrolled patients, ORR was 75.0%. In total, 33 patients received surgery (all achieving R0 resection) after 1-4 cycles of induction chemoimmunotherapy, and the MPR rate was 66.7% (22/33). The median EFS and OS for the entire study cohort were 17.7 months and not reached, respectively. Among randomized patients, the hazard ratio for surgery versus radiotherapy in EFS in the intention-to-treat and per-protocol populations were 0.38 (95% CI: 0.14-1.01) and 0.21 (95% CI: 0.06-0.66), respectively. While, no significant difference in OS was observed. SAE and grade 3-5 treatment-related adverse event rates in induction therapy phase were 12.0% and 58.0%, respectively.

Conclusions

Induction chemoimmunotherapy showed good efficacy and safety in unresectable stage IIIB-IIIC NSCLC, and surgery brought longer EFS than radiotherapy.

Clinical trial identification

NCT05766800.

Legal entity responsible for the study

Shanghai Pulmonary Hospital.

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Disclosure

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