chemotherapy and stereotactic ablative radiotherapy in newly diagnosed and recurrent locally advanced non-small cell lung cancer patients unfit for concurrent chemotherapy: sub-analysis and update of START NEW ERA non-randomized phase II trial

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Aims

Early analysis [1] of a single arm phase II trial (Clinical trials.gov NCT05291780) assessed local control (LC) and safety of stereotactic ablative radiotherapy (SAbR) unresectable locally advanced non-small cell lung cancer (LA-NSCLC) patients unfit for concurrent chemoradiotherapy (ChT-RT). Here we report clinical outcomes of LA-NSCLC patients submitted to neoadjuvant ChT and SAbR.

Methods

Between December 31, 2015 and June 30, 2022 71 LA-NSCLC patients were enrolled. 40 (56%) and 31 (44%) received neoadjuvant ChT + SAbR and exclusive SAbR, respectively. Among 40 (56%) patients receiving ChT, 15 (37%) received Durvalumab. The tumor volume included primary tumor (T) and any regionally positive node/s (N). The co-primary study endpoints were LC and safety.

Results

The median age was 71 years (range, 52-85). 36 (90%) and 4 (10%) patients had PS 0-1 and 2, respectively. Histology was squamous cell carcinoma (SCC) and adenocarcinoma (ADC) in 52% and 48%, respectively. The stage was IIB, IIIA, IIIB and IIIC in 4 (10%), 13 (33%), 17 (42%) and 6 (15%) patients, respectively. Median prescribed dose was 45 Gy (range, 35-55) and 40 Gy (35-45) in 5 daily fractions to T and N, respectively. After a median follow-up of 26 months (range, 6-66), 14 (35%) patients had experienced local recurrence (LR) at a median time of 13 months (range, 7-34). The median LR-free survival (FS) was not reached (95% CI, 28 to not reached). The 1-, 2- and 4-year LR-FS rates were 86±6%, 67±8% and 50±10%, respectively. At last follow-up, 23 (58%) patients were alive. Median overall survival (OS) was 50 months (95% CI, 31-55). The 1, 2, and 4-year OS rates were 92±5%, 70±8% and 51±9%, respectively. 14 (35%) patients developed distant progression (dP). The median dP-FS was not reached (95% CI, 16 to not reached). The 1, 2, and 4-year dP-FS rates were 86±6%, 56±9% and 56±9%, respectively. The compliance to treatment was 100% and 2 (5%) patients developed grade (G) ≥ 3 esophageal and lung toxicity.

Conclusions

LA-NSCLC patients treated with ChT and SAbR had optimal LC and promising OS with low rate of G3 toxicity. Our early outcomes would suggest the feasibility of using this approach in LA-NSCLC patients unfit for concurrent ChT-RT.


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NO conflict of interest to declare