Exclusive stereotactic ablative radiotherapy in LA-NSCLC patients: little palliation or big cure? sub-analysis of START NEW ERA phase II trial

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Aims

Early analysis [1] of a single arm phase 2 trial (Clinical trials.gov NCT05291780) assessed local control (LC) and safety of stereotactic ablative radiotherapy (SAbR) unresectable LA-NSCLC patients unfit for concurrent chemo-radiotherapy (ChT+RT). Here we report clinical outcomes of LA-NSCLC patients submitted to exclusive 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. The tumor volume included primary tumor (T) and any regionally positive node/s (N). The coprimary study endpoints were LC and safety.

Results

The median age was 80 years (range, 45-88). Twenty (64%) and eleven (36%) patients had PS 0-1 and 2, respectively. Histology was adenocarcinoma (ADC) and squamous cell carcinoma (SCC) in 71% and 29%, respectively, 27 (87%) patients had ultra-central tumor. 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 27 months (range, 6-92), 9 (29%) 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 81±7%, 66±9% and 66±9%, respectively. At last follow-up, 23 (74%) patients were alive. Median overall survival (OS) was not reached. The 1, 2, and 4-year OS rates were 97±3%, 74±8% and 70±9%, respectively. Eight (26%) patients developed distant progression (dP). The median dP-FS was not reached (95% CI, 26 to not reached). The 1, 2, and 4-year dP-FS rates were 82±7%, 72±9% and 66±10%, respectively. The compliance to treatment was 100% and no patients developed grade (G) ≥ 3 toxicity.

Conclusions

LA-NSCLC elderly patients treated with exclusive SABR had optimal local control and promising overall survival with excellent treatment compliance and absence of ≥G3 toxicity. Our preliminary prospective clinical outcomes provide an attraction to evaluate this approach in elderly patients unfit to ChT, to obtain a “big” cure beyond “little” palliation.


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NO conflict of interest to declare