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Patient reported outcomes from a randomized phase II trial comparing standard-dose with high-dose twice daily (BID) thoracic radiotherapy (TRT) in limited stage small cell lung cancer (LS SCLC)

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Background

Concurrent chemoradiotherapy is the standard treatment of LS SCLC. BID TRT of 45 Gy is the most recommended schedule. Only 30% are cured, and there is a need for better treatment. A higher TRT dose might improve local control and survival, and we conducted a phase II trial comparing BID TRT of 45 Gy with 60 Gy. There have been major concerns about toxicity from BID TRT. Here we present the patient reported health-related quality of life (HRQoL) from our trial.

Methods

Patients received 4 courses of platinum/etoposide (PE) and were randomized to receive TRT of 45 or 60 Gy after the second PE-course. Responders received prophylactic cranial irradiation (PCI) of 25-30 Gy. Patients reported HRQoL on the EORTC QLQ C30/LC13 at weeks 0, 4 (before TRT), 8 (end of TRT), 12 (response evaluation), 16 (end of PCI), 22, 32, 42 and 52. Primary HRQoL-endpoints were dysphagia, dyspnea, global QoL and physical function. A difference in mean score of ≥10 was considered clinically relevant.

Results

Between 2014-2018, 160 patients eligible for the present analyses were enrolled. Median age was 65, 58% women, 10% had PS 2 and 81% stage III. There were no significant differences in objectively assessed toxicity, and there was less radiotoxicity than in many previous studies. The high-dose arm achieved a significantly improved 2-year survival (primary endpoint) (46% vs. 70%; p=.002) and median overall survival (23 vs. 42 months; p=.027). The completion rate of questionnaires at each timepoint ranged from 61%-76%. Patients reported an increase in dysphagia from TRT with a max. level at w8 (45 Gy: mean score 45.1 points, 60 Gy: 51.9). 60 Gy patients had more dysphagia at w12 (45 Gy: 18.3, 60 Gy: 32.8) and w16 (45 Gy: 7.3, 60 Gy: 18.4), but after w22, the level of dysphagia returned to pre-treatment values in both arms. There were no significant differences in dyspnea, global quality of life or physical functioning, or on any other HRQoL scales, at any timepoint.

Conclusions

High-dose BID TRT significantly improved survival and was well tolerated both in terms of toxicity and patient reported HRQoL, though some patients on the high-dose arm needed a longer time to recover from radiation-induced dysphagia.

Clinical trial identification

NCT02041845.

Legal entity responsible for the study

NTNU-Norwegian University of Science and Technology.

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Disclosure

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