Lectureship Awards IASLC WCLC 2017 Yokohama, Dirk De Ruysscher

MA 17 - Locally Advanced NSCLC (ID 671)

15:45 - 17:30 | 10/17/2017 | Location: F203 + F204 (Annex Hall)

Type: **Mini Oral** | Track: **Locally Advanced NSCLC**

Moderators: S. Jheon, Georgios Stamatis

MA 17.10 - Toxicity Results from the Randomized Phase III NVALT-11 Study of Prophylactic Cranial Irradiation vs. Observation in Stage III NSCLC (ID 9262)

16:50 - 16:55 | Presenting Author(s): Dirk K De Ruysscher | Author(s): Anne-Marie C. Dingemans, J. Praag, J. Belderbos, C. Tissing-Tan, J. Herder, T. Haitjema, F. Ubbels, F.J. Lagerwaard, J. Stigt, Egbert F Smit, H. Van Tinteren, V. Van Der Noort, H.J. Groen

Abstract

Background:
NVALT-11 randomized trial showed that PCI reduced the proportion of stage III NSCLC patients with symptomatic BM from 28 % to 5 % (Groen ASCO 2017). Here, we report on the toxicity.

Method:
We randomized between PCI or observation in radically treated stage III NSCLC. Primary endpoint: incidence of symptomatic brain metastases; secondary endpoints: OS, toxicity and quality of life.

Result:
Between 2009 and 2015 a total of 195 pts were registered, 175 were randomized, 87 received PCI and 88 pts were in the observation arm. Median follow up: 48.5 months (95% CI, 39-54). Neurological adverse events (AE) of all grades that occurred more frequently in the PCI vs. the observation arm: cognitive disturbance (18 vs. 2 pt; p< 10[-4]) and memory impairment (25 vs. 7 pt; p<10[-3]). No significant difference in G3-4 cognitive disturbance and memory impairment. Non-neurological AE of all grades that were more frequent in the PCI arm: alopecia (36 vs. 5 pt; p<10[-6]), fatigue (55 vs. 29 patients; p<10[-4]), nausea (30 vs. 15 patients; p=0.01), anorexia (6 vs. 0 patients; p=0.01) and dysphagia (11 vs. 2 pt; p=0.01). Of the G3-4 AE, only fatigue was significantly more present in the PCI arm (13 vs. 2 pt, p < 0.01). Scored as treatment-related, neurological toxicities of all grades that occurred more frequently in the PCI vs. the observation arm: cognitive disturbance (7 vs. 0 pt; p=0.01), dizziness (7 vs. 0 pt; p=0.01) and memory impairment (14 vs. 0 pt; p<10[-4]). No significant differences in G3-4 toxicities, with only one patient reporting severe cognitive disturbance in the PCI group. Scored as treatment-related, non-neurological toxicities of all grades that were more frequent in the PCI arm: alopecia (26 vs. 1 pt; p<10[-6]), fatigue (19 vs. 2 patients; p<10[-4]), nausea (16 vs. 0 patients; p<10[-5]), headache (19 vs. 1 pt; p<10[-5]), rash (8 vs. 0 pt; p<0.01) and vomiting (9 vs. 0 pt; p<0.01). No significant differences in G3-4 toxicities, with 3 patients reporting severe fatigue, 2 nausea and 1 vomiting, all in the PCI group. Overall QoI was worse in the PCI arm 3 months post-treatment, but was similar to observation thereafter.

Conclusion:
PCI related symptoms were mainly grade 1-2 memory and cognitive disturbances and fatigue. G3-4 toxicities were very rare. QoL was only temporarily affected by PCI. The side effects of PCI should be balanced against deteriorating BM symptoms and the lack of OS benefit (Groen ASCO 2017).