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CAN WE PREDICT SEVERE ADVERSE EVENTS (SAEs) AND CLARIFY UNFIT POPULATIONS FOR PLATINUM-BASED CHEMOTHERAPY IN ELDERLY PATIENTS (OVER 70 YEARS OF AGE) WITH ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)? (CJLSG 1203 TRIAL)

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Aim: Platinum-based therapy has shown survival benefits in elderly patients with NSCLC. The aim of this multicenter retrospective cohort study was to identify the risk factors for the development of SAEs and explore the prediction of elderly patients unfit for platinum-based therapy.

Methods: Data of 198 consecutive elderly patients treated with platinum-based therapy between 2010 and 2012 were reviewed. Unfit elderly was defined as patients who developed an event of early termination of treatment (in 1-2 cycles) without disease progression. We focused on non-hematological (non-H) -SAEs (grade 3-5) and hematological (H)-SAEs (grade 4-5) in early phase (1-2 cycles), and explored the association between AEs and early termination of treatment.

Results: Patient characteristics were as follows: male/female 161/37; median age 73 years (range 70-83); PS 0-1/2 190/8; non squamous cell carcinoma (Sq)/Sq 144/54. The majority of drugs in combination were pemetrexed (42%) and paclitaxel (30%). The median overall survival (OS) was 11.9 months. 44 (22%) and 39 (19%) developed non-H- and H-SAEs in early phase, respectively. Multivariate analysis identified the baseline low serum albumin (low Alb) (≤3.0 g/dl) as an independent risk factor for the development of non-H-SAEs [adjusted odds ratio (AOR): 2.75, (95% CI: 1.18-6.30)], while the baseline low creatinine clearance (<45 ml/min) for the development of H-SAEs [AOR: 6.13, (95% CI: 1.63-25.48)]. The median overall survival (OS) was 11.9 months. 44 (22%) and 39 (19%) developed non-H- and H-SAEs in early phase, respectively. Multivariate analysis identified the baseline low serum albumin (low Alb) (≤3.0 g/dl) as an independent risk factor for the development of non-H-SAEs [adjusted odds ratio (AOR): 2.75, (95% CI: 1.18-6.30)], while the baseline low creatinine clearance (<45 ml/min) for the development of H-SAEs [AOR: 6.13, (95% CI: 1.63-25.48)]. The median overall survival (OS) was 11.9 months. 44 (22%) and 39 (19%) developed non-H- and H-SAEs in early phase, respectively. Multivariate analysis identified the baseline low serum albumin (low Alb) (≤3.0 g/dl) as an independent risk factor for the development of non-H-SAEs [adjusted odds ratio (AOR): 2.75, (95% CI: 1.18-6.30)], while the baseline low creatinine clearance (<45 ml/min) for the development of H-SAEs [AOR: 6.13, (95% CI: 1.63-25.48)]. The median overall survival (OS) was 11.9 months. 44 (22%) and 39 (19%) developed non-H- and H-SAEs in early phase, respectively. Multivariate analysis identified the baseline low serum albumin (low Alb) (≤3.0 g/dl) as an independent risk factor for the development of non-H-SAEs [adjusted odds ratio (AOR): 2.75, (95% CI: 1.18-6.30)], while the baseline low creatinine clearance (<45 ml/min) for the development of H-SAEs [AOR: 6.13, (95% CI: 1.63-25.48)]. The median overall survival (OS) was 11.9 months. 44 (22%) and 39 (19%) developed non-H- and H-SAEs in early phase, respectively. Multivariate analysis identified the baseline low serum albumin (low Alb) (≤3.0 g/dl) as an independent risk factor for the development of non-H-SAEs [adjusted odds ratio (AOR): 2.75, (95% CI: 1.18-6.30)], while the baseline low creatinine clearance (<45 ml/min) for the development of H-SAEs [AOR: 6.13, (95% CI: 1.63-25.48)].

Conclusions: In addition to non-H-SAEs, grade 2 non-H-AEs affected the continuation of platinum-based therapy. Baseline Alb would be useful for predicting the risk of non-H-SAEs and unfit elderly in platinum-based therapy.

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