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FINAL RESULTS OF A RANDOMIZED PHASE 2 STUDY COMPARING CARBOPLATIN PLUS IRINOTECAN (CI) VERSUS CARBOPLATIN PLUS AMRUBICIN (CA) FOR EXTENSIVE DISEASE SMALL-CELL LUNG CANCER: NJLCG0901


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Aim: Cisplatin-based regimens are standard first-line chemotherapy for extensive-disease small-cell lung cancer (ED-SCLC). In patients (pts) unfit for cisplatin due to advanced age or poor performance status (PS), carboplatin plus etoposide (CE) is as effective as cisplatin plus etoposide (JCOG9702 trial), although its efficacy is not satisfactory. Carboplatin plus irinotecan (CI) and carboplatin plus amrubicin (CA) are promising new carboplatin-based regimens identified in our previous studies (NJLCG0405 and NJLCG0711). Accordingly, we conducted this randomized phase 2 study to compare these two regimens to select the more appropriate candidate for future phase 3 trials.

Methods: Chemotherapy-naive ED-SCLC pts were randomly assigned to receive 4-6 cycles of carboplatin (area under the curve [AUC] 5.0, day 1) plus irinotecan (70mg/m2, days 1 and 8) every 3 weeks (CI) or carboplatin (AUC 4.0, day 1) plus amrubicin (mg/m2, days 1-3) every 3 weeks (CI). The primary endpoint was the overall response rate (ORR). The secondary endpoints were progression-free survival (PFS), overall survival (OS), and toxicity. Assuming that an ORR of 80% in eligible pts indicates potential usefulness and an ORR of 60% is the lower limit of interest, the target sample size was 35 pts in each arm (alpha, 0.05; beta, 0.80).

Results: Between December 2009 and March 2013, 71 pts were enrolled. One patient in CI and one patient in CA did not receive any protocol treatment due to rapid disease progression. Pt median age was 70 (51-84), with 16% female, and 91% of pts had good PS (0-1). The ORRs were 79% (95% confidence interval [CI]: 62-91) and 89% (95%CI: 73-93), median PFS were 5.1 and 6.2 months (hazard ratio [HR]=0.59, 95%CI: 0.35-0.98, p=0.042), and median overall survival were 12.2 months and 15.9 months with CI and CA, respectively. In the elderly (not less than 70), CA showed similar favorable effects compared with CI as well as less than 70. Toxicities of grade 3 or higher severity were neutropenia (CI, 53% and CA, 89%), anemia (CI, 26% and CA, 20%), thrombocytopenia (CI, 18% and CA, 14%), and febrile neutropenia (CI, 12% and CA, 29%). No treatment-related deaths were observed.

Conclusions: CA was numerically more effective than CI in chemo-naive ED-SCLC, with acceptable toxicity. This regimen could be selected for phase 3 trials.

Disclosure: All authors have declared no conflicts of interest.