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A PHASE II TRIAL OF FIRST-LINE NAB-PACLITAXEL/CARBOPlatin VERSUS GEMcitABINE/Carboplatin IN ADVANCED SQUAMOUS CELL CARCINOMA OF THE LUNG (CTONG1002)

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Aim: The administration of nab-paclitaxel/carboplatin (nab-PC) as first-line therapy in patients with advanced non-small-cell lung cancer was efficacious and resulted in a significantly improved objective overall response rate (ORR) versus solvent-based PC in a phase II trial. Subgroup analysis showed the squamous histology appeared to be a predictive factor to nab-paclitaxel treatment. This phase II trial (NCT01236716; CTONG1002) compared the efficacy and safety of first-line nab-PC with gemcitabine/carboplatin (GC) in advanced squamous cell carcinoma of the lung.

Methods: From November 2010 to June 2013, 127 untreated patients with locally advanced and metastatic squamous cell carcinoma of the lung were randomly assigned 1:1 to receive first-line nab-PC (nab-P, 135mg/m², d1,d8, q3w; C, AUC = 5, d1, q3w) or GC (G, 1250mg/m², d1, d8, q3w; C, AUC = 5, d1, q3w). The primary endpoint was ORR. The secondary endpoints were progression-free survival (PFS), overall survival (OS), safety and quality of life (QoL).

Results: There were 110 cases evaluable for ORR (nab-PC, 54; GC, 56), 119 evaluable for survival (nab-PC, 57; GC, 62) and 124 evaluable for safety (nab-PC, 59; GC, 65), respectively. ORR was 46.3% (25/54) for the nab-PC arm and 30.4% (17/56) for the GC arm respectively, p = 0.085. There was an approximately 18.8% improvement in PFS (median, 5.7 v 4.8 months; hazard ratio [HR], 0.907; 95%CI, 0.588 to 1.399; p = 0.657) in the nab-PC arm versus the GC arm. OS was not significantly different between the two arms (median, 11.9 v 14.4 months; HR, 1.010; 95%CI, 0.640 to 1.590; p = 0.970). Significant grade ≥3 leucopenia (41.7% v 17.2%, p<0.010) and neutropenia (70.0% v 42.2, p<0.010) occurred in the nab-PC arm. Improvement of QoL favored the nab-PC arm, but there was no significant difference between the two arms (Total FACT-L, 72.9% v 58.1%, p = 0.160; LCS, 76.7% v 75.0%, p = 0.670; TOI, 75.0% v 57.8%, p = 0.050).

Conclusions: First-line nab-PC in advanced squamous cell carcinoma of the lung was efficacious and resulted in a marginally improved ORR versus GC, but not achieving the primary endpoint. There was no significant difference in terms of survival and QoL between the two arms. The overall adverse events of nab-PC were manageable though more leucopenia and neutropenia were observed in nab-PC arm than with GC.

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