SCLC

1474P  RANDOMIZED PHASE II STUDY OF BELOTECAN OR TOPOTECAN CHEMOTHERAPY AS SECOND-LINE CHEMOTHERAPY AFTER PLATINUM-BASED FIRST-LINE CHEMOTHERAPY FOR SMALL CELL LUNG CANCER

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Aim: Topotecan has been accepted as second-line therapy for small cell lung cancer (SCLC), in addition, belotecan also been reported to have a significant response rate. Based on these results, we designed prospective randomized phase II trial of belotecan as a second-line treatment in patients with SCLC, who experienced disease progression within 6 months after first-line platinum-containing chemotherapy or chemo-radiotherapy.

Methods: We randomly assigned patients to belotecan 0.5 mg/m² (n=61) or topotecan 1.5 mg/m² (n=55) for 5 days every 21 days, stratified by response to first-line chemotherapy. The primary end point was response rate (RR). The secondary end points were progression-free survival (PFS), overall survival (OS) and safety profiles.

Results: From August 2006 to December 2013, a total of 116 patients were enrolled. The median age was 64 years (range, 28-82), and the ratio of males to females was 0.89. In total, 186 cycles of topotecan (median 2, range 1-9) and 180 cycles of belotecan (median 2, range 1-8) were administered. Median follow-up was 5.6 months. RR of belotecan and topotecan was 19.7% (12/61) and 18.2% (10/55), respectively (p=0.92). Median PFS and OS of belotecan and topotecan was 2.1 months (95% CI 1.43-2.72) versus 2.3 months (1.46-3.07) and 11.2 months (10.2-12.1) versus 12.1 months (10.1-14.0), respectively (p=0.167, 0.659). Grade 3/4 hematologic adverse events with belotecan and topotecan were anemia [13.1% versus 14.5% (p=1.000)], thrombocytopenia [3.3% versus 7.3% (p=0.421)], neutropenia [21.3% versus 43.6% (p=0.016)].

Conclusions: Belotecan showed comparable efficacy to that with topotecan and more favorable toxicity profiles for neutropenia.

Disclosure: All authors have declared no conflicts of interest.